

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 589

[Docket No. 01N-0423]

DMB

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Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments..

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing in Kansas City, MO, to solicit information and views on its present animal feeding regulation. The purpose of the rule is to help prevent the establishment and amplification of the agent(s) of bovine spongiform encephalopathy (BSE) in the U.S. cattle herd through feed and thereby help minimize any risks from such agent(s) to animal or human health. FDA recognizes that much new information has emerged on BSE and new variant Creutzfeldt-Jakob Disease (vCJD) since the rule went into effect in 1997. FDA is therefore requesting information and views from individuals and organizations on the present rule and whether changes in the rule or other additional measures are necessary. The agency is particularly interested in soliciting comments and views from individuals, industry, consumer groups, health professionals, and researchers with expertise in BSE and related animal and human diseases.

DATES: The hearing will be held on October 30, 2001, from 9 a.m. to 5 p.m. central time and will be open to the public throughout its entirety. The hearing will be adjourned from 12 noon to 1 p.m. for lunch. FDA will reserve the hour from 4 p.m. to 5 p.m. for those who have not registered to present orally at the meeting to make oral presentations to the panel. Those individuals or organizations that wish to register to present orally at the hearing must register by 4:30 p.m.

eastern time on October 23, 2001. Send registration information to the contact person. Written comments regarding the matters before this panel are welcome at anytime; however, the official record of the hearing will remain open to receive written comments until November 21, 2001.

ADDRESSES: The public hearing will be held at the Westin Crowne Center Hotel, One Pershing Rd., Kansas City, MO. Those wishing to present orally at the hearing must submit a written notice of participation to Linda Grassie at the address or fax number listed in **FOR FURTHER INFORMATION CONTACT** section. To submit electronic comments go to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>.

Individuals and organizations wishing to submit written comments on these issues to the panel, but who do not wish to present orally to the panel, should submit their written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Written comments are to be identified with Docket No. 01N-0423.

Information specified in this notice can be received by calling 301-594-5000 or sending a self-addressed stamped envelope with your request to the contact person listed below.

FOR FURTHER INFORMATION CONTACT: Linda Grassie, Center for Veterinary Medicine (HFV-12), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-3796, FAX 301-827-4065, e-mail lgrassie@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 5, 1997 (62 FR 30936), FDA issued a final rule amending its final regulations to provide that animal protein derived from mammalian tissues for use in ruminant feed is a food additive subject to certain provisions in the Federal Food, Drug, and Cosmetic Act. The final rule established at § 589.2000 (21 CFR 589.2000) a flexible system of controls, including a number of exemptions, designed to ensure that ruminant feed does not contain most mammalian tissue proteins and to encourage innovation in such controls. FDA issued this regulation to protect animal and human health in the United States. The final rule was intended

to help prevent the establishment and amplification of BSE in the U.S. cattle herd through feed, and thereby help minimize any risk from the agent(s) of BSE to animals or humans health.

This rule has now been in effect for 4 years. Federal, State, and private sector entities have conducted an intensive campaign to educate livestock producers and all sectors of the animal feed industry on the purpose of the rule and the requirements for compliance with the rule. Since 1997, FDA and State feed inspectors have conducted over 10,000 inspections of cattle producers and firms involved in the manufacture of animal feeds. The inspectors found approximately 78 percent of these firms to be in compliance with this rule. Upon re-inspection, inspectors found approximately 90 percent of the firms to be in compliance with the rule. In addition, there have been incidents in which feed containing prohibited materials has been fed to cattle. To date, there is no evidence that this feed contained prohibited proteins that were infected with the agent(s) of BSE. All known instances of feeding violations involved animal protein from countries free of BSE.

To date, there has been no evidence of BSE or vCJD in the United States. Nonetheless, since the promulgation of this rule, BSE has spread and is now found in most countries of western and central Europe and, pending final confirmation, Japan. New efforts this year to contain the spread of the epidemic in Europe have included, among other policies, a ban on feeding most animal protein to farmed animals.

II. Scope of the Hearing

There are many evolving, complex scientific and public health issues involved in the effort to prevent the establishment and amplification of the agent(s) of BSE in the U.S. cattle herd and to reduce the risk to American public health from the agent(s) of BSE. In light of these issues, FDA is soliciting broad public participation and comment on issues regarding whether new measures are necessary in addition to FDA's present animal feeding rule at § 589.2000 and regarding the compliance with that rule to date. Because of the spread of BSE beyond the United Kingdom, and because of the compliance experience to date with the 1997 rule, FDA believes

it would be prudent to solicit information and views on the present rule and if there are ways in which this rule and its enforcement might be further improved to meet its original objectives or any new objective(s) that may now be appropriate to consider.

Since 1997, FDA has received numerous unsolicited suggestions from many individuals and groups regarding this rule. These have ranged from making no changes to the rule to completely banning the use of all animal proteins in the feeding of all animals. In addition, there have been many suggestions that would fall between these two positions.

The agency encourages individuals, industry, consumer groups, health professionals, and researchers with particular expertise in this area, as well as other interested persons, to respond to this notice. The agency strongly encourages persons who cannot attend the hearing to send information and views relevant to the topics and questions listed below in this document to the Dockets Management Branch (address above). Comments should be identified with Docket No. 01N-0423.

FDA is soliciting information and comments on all aspects of the present feeding rule at § 589.2000 and specifically requests comments on the following questions. For each question, FDA is requesting information and comments on the impact on public health and on both animal feed and human food safety, on any increased business costs that might result from such changes, and any suggestions on ways to minimize any potential increased costs or any relevant environmental concerns associated with such changes. Individuals and organizations may address as many of the following questions as they wish. It is not expected that all participants will address all questions.

1. What additional enforcement activities, if any, regarding the present rule are needed to provide adequate public health controls? Are there other suggestions for ways to improve compliance with the rule?

2. Is the present rule at § 589.2000 adequate to meet its intended objectives? If not, what are its inadequacies? Are there additional objectives that this rule should now address? If so, what are these new objectives?

3. Should the present FDA ban on the use of certain mammalian proteins in ruminant feed be broadened? If so, what should the new parameters of use be? Should the rule be broadened beyond ruminant feed? Beyond mammalian protein?
4. Should FDA require dedicated facilities for the production of animal feed containing mammalian protein to decrease as much as possible the possibility of comingling during production?
5. Should FDA require dedicated transportation of animal feed containing mammalian protein to decrease as much as possible the possibility of comingling during transport?
6. In order to improve production practices and increase assurance of compliance with the rule, should FDA require FDA licensing of renderers and other firms/facilities engaged in the production of animal feed containing mammalian protein?
7. Should FDA revoke or change any/all of the current exclusions for certain products allowed in the current rule at § 589.2000(a)(1)?
8. Should FDA add to the list of prohibited material in ruminant feed (i.e., add to the definition of "protein derived from mammalian tissues") poultry litter and other recycled poultry waste products?
9. Should FDA remove the exemption for pet foods from labeling with the precautionary statements?
10. Should FDA extend its present recordkeeping requirements beyond 1 year? If so, how many years?
11. Should FDA change its rule to require labeling of protein-containing feed to specify what type(s) of mammal was used in the production of the protein, e.g. "porcine MBM", "bovine MBM".
12. In order to make the statement clearer, should the required cautionary statement on the label of products that contain protein derived from mammalian tissues and that are intended for use in animal feed be changed to read: "Do not feed to cattle, sheep, goats, bison, elk, or deer."?

13. What new information is available on potential efficient, accurate analytical methods that may be used in detecting mammalian proteins, especially the prohibited mammalian proteins, in feed and what should the sampling parameters of such a program be?

14. Regarding enforcing compliance with the rule, what further authorities, if any, would be desirable in order to enforce the rule adequately (civil monetary penalties?, others?)

15. Regarding helping to increase compliance with the rule, what role, if any, should public or private certification programs play?

16. Regarding the import of feed, what should the restrictions on such import be (country specific? comparison between domestic and foreign controls?)

17. Are there any other additional measures necessary to guard against BSE and vCJD in the United States?

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Commissioner of Food and Drugs or his designee. A panel of government employees with relevant expertise will accompany the presiding officer.

Persons who wish to participate in the part 15 hearing must file a written or facsimile notice of participation with Linda Grassie (address or fax number above) by 4:30 p.m. eastern time on October 23, 2001. To ensure timely handling, the outer envelope should be clearly marked with Docket No. 01N-0423 and the statement "Animal Feed Rule Hearing." Groups should submit two copies. The notice of participation should contain the speaker's name, address, telephone number, fax number, business affiliation, if any, a brief summary of the presentation, and approximate amount of time requested for the presentation.

The agency requests that persons or groups having similar interests consolidate their presentations and present them through a single representative. FDA will allocate the time available for the hearing among the persons who properly file notices of participation. FDA will reserve

the hour from 4 p.m. to 5 p.m. for those who have not registered to present orally at the meeting to make oral presentations to the panel.

After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by mail, telephone, or fax, of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. The hearing schedule will be available at the hearing. After the hearing, the schedule will be placed on file in the Dockets Management Branch (address above) under Docket No. 01N-0423.

In order to facilitate the efficiency of the hearing process, presenters at the hearing should indicate the format in which their presentations will be made so that appropriate visual aids can be made available. Presenters should note that a hardcopy version of their presentations should be submitted to FDA on the day of the hearing for inclusion in the official record of the hearing.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. The presiding officer and any panel members may question any person during or at the conclusion of their presentation. No participant may interrupt the presentation of another participant.

Public hearings under part 15 are subject to FDA's policy and procedures (part 10 (21 CFR part 10, subpart C)) for electronic media coverage of FDA's public administrative proceedings. Under § 10.205, FDA permits persons, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as required in § 15.30(b).

Any disabled persons requiring special accommodations in order to attend the hearing should direct those needs to the contact person listed above.

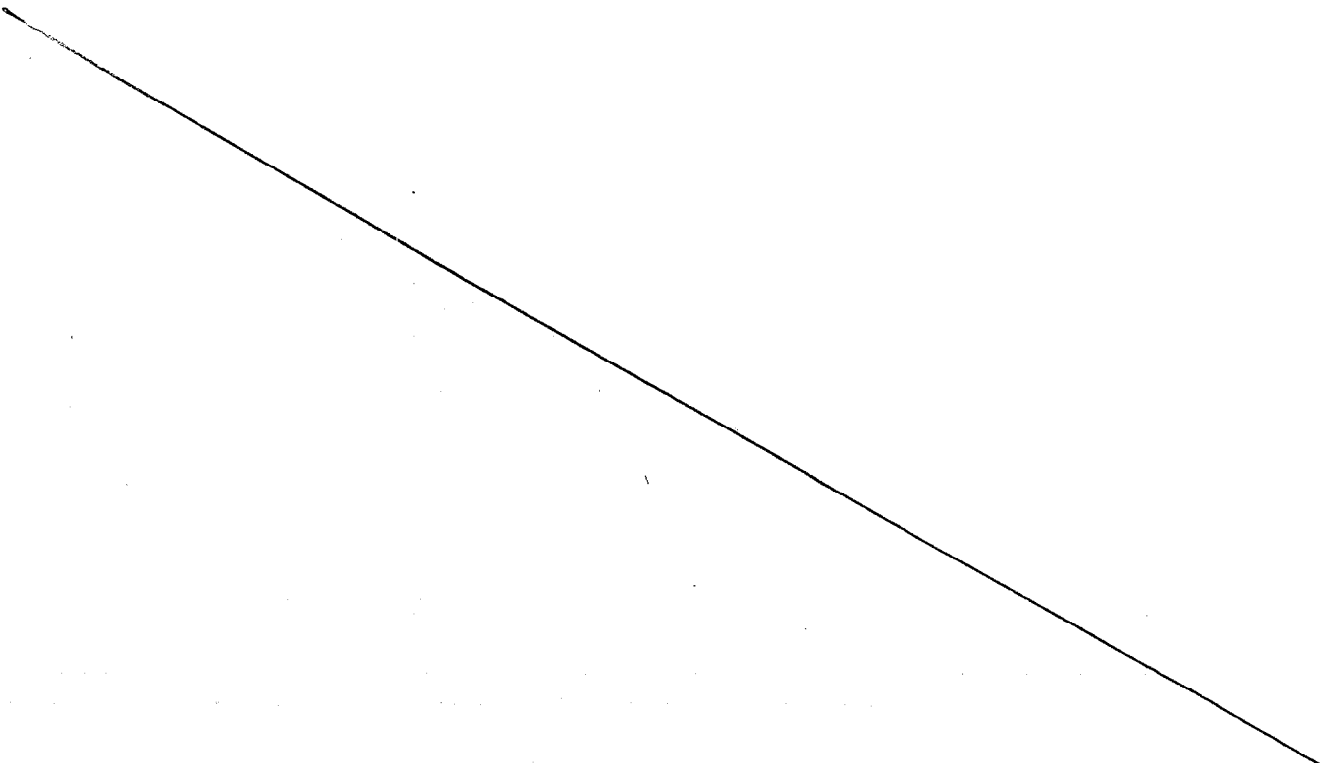
To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

IV. Request for Comments

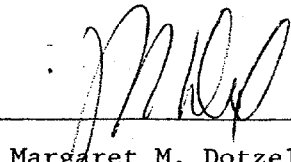
To permit time for all interested persons to submit data, information, or views on this subject, interested persons may submit to the Dockets Management Branch written comments for this hearing at any time; however, the official record of the hearing will remain open to receive written comments until November 21, 2001. Such written comments can be submitted to the Dockets Management Branch (HFA-305), Animal Feed Rule Hearing, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or FAX written comments to the Dockets Management Branch, Animal Feed Rule Hearing, 301-827-6870. Two copies of any comments are to be submitted, except individuals should submit one copy. Comments are to be identified with Docket No. 01N-0423.

V. Transcripts

Transcripts of the hearing will be available for review at the Dockets Management Branch (address above) approximately 30 days following the hearing and at <http://www.fda.gov>; also orders can be placed with Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857.



Dated: 10/1/01
October 1, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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